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DEC 09 2009
PATENT & TRADEMARK OFFICE

Docket No.: **94-P0273US19**
[209.1610039]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	09/977,826
Applicants:	:	George Goicoechea, et al.
Filed:	:	October 15, 2001
TC/A.U.	:	3774
Examiner:	:	ENDOLUMINAL STENT
Title:	:	

APPELLANTS' REPLY BRIEF TO EXAMINER'S ANSWER DATED SEPTEMBER 30, 2009 (37 CFR 41.41)

MS APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir or Madame:

This Reply Brief, in compliance with 37 C.F.R. § 41.41, is in response to the Examiner's Answer dated September 30, 2009, and in furtherance of the Notice of Appeal filed under 37 C.F.R. § 41.31 on June 12, 2008.

The Examiner's Grounds for Rejection are substantially the same as those presented in the Final Office Action (FOA) dated March 24, 2008. Appellant has addressed these rejections in the Appeal Brief dated May 28, 2009.

In the Examiner's Answer dated September 30, 2009, the Examiner provides a response to the arguments presented in the Appeal Brief. Appellant respectfully traverses the assertions and conclusions provided in the Examiner's response. The following is the Appellant's Reply Brief in response to the Examiner's Answer dated September 30, 2009, which incorporates the Appeal Brief that was previously filed. Material provided in response to the Examiner's Answer has been included as addenda and has been marked accordingly.

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This brief contains items under the following headings as required by 37 C.F.R. § 41.37:

I. Real Party In Interest

II. Related Appeals and Interferences

III. Status of Claims

IV. Status of Amendments

V. Summary of Claimed Subject Matter

VI. Grounds of Rejection to be Reviewed on Appeal

VII. Argument

VIII. Claims Appendix

IX. Evidence Appendix

X. Related Proceedings Appendix

Page 22 of this brief bears the attorney's signature.

I. REAL PARTY IN INTEREST

The real Party In Interest in this matter is Boston Scientific Scimed, Inc. by virtue of Articles of Merger of Boston Scientific Scimed, Inc. with and to Scimed Life Systems, Inc. dated December 22, 2004.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences related to the subject matter of this Appeal, except as follows:

Interference No. 104,083. A copy of the Judgment of the Board of Patent Appeals and Interferences in this Interference was provided in the Related Proceedings Appendix (Section X) at Tab 1 of the Appeal Brief filed May 28, 2009. This Interference involved related Application Serial No. 08/461,402 of Andrew H. Cragg et al., filed June 5, 1995, titled BIFURCATED ENDOLUMINAL PROSTHESIS.

Interference No. 104,192. A copy of the Final Decision and Judgment of the Board of Patent Appeals and Interferences in this Interference was provided in the Related Proceedings Appendix (Section X) at Tab 2 of the Appeal Brief filed May 28, 2009. This Interference also involved related Application Serial No. 08/461,402.

Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL). This was an appeal from the Board's decision in Interference No. 104,192. The following interlocutory orders, and/or decisions, memorandum opinion, and final judgment were entered in that appeal, with copies that were included in the Related Proceedings Appendix (Section X) at the indicated Tabs of the Appeal Brief filed May 28, 2009:

DATE	ORDER OR OPINION	TAB
11/15/01	Order	3
12/21/01	Order	4
5/2/02	Order	5
8/30/03	Memorandum Opinion and Order	6

3/25/04	Stipulation and Order	7
9/12/04	Protective Order	8
12/14/04	Joint Stipulated Request To Extend Discovery	9
3/31/06	Memorandum Opinion	10
3/31/06	Final Judgment	11

Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.) v. Medtronic Vascular, Inc. (also known as Medtronic AVE, Inc.), United States Court of Appeals for the Federal Circuit, No. 2006-1434. This was an appeal from the decision of the U.S. District Court for the District of Columbia. A copy of the decision of the Federal Circuit is provided in the Related Proceedings Appendix (Section X) at Tab 12.

III. STATUS OF CLAIMS

Claims 20, 22-41, 43-49 and 54-62 are pending. Claims 26, 34-38, 40, and 58-62 have been withdrawn from consideration. Claims 1-19, 21, 42, 50-53 have been canceled. Claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 stand rejected and are being appealed. A copy of the rejected claims is provided in the Claims Appendix (Section VIII).

To assist the Board in correlating dependent claims with their corresponding independent claims, appellants provide the following chart of the pending claims that have not been withdrawn:

20	Dependent on claim 54
22	Dependent on claim 20
23	Dependent on claim 20
24	Dependent on claim 20
25	Dependent on claim 20
27	Dependent on claim 20
28	Dependent on claim 27
29	Dependent on claim 28
30	Dependent on claim 29
31	Dependent on claim 54
32	Dependent on claim 54
33	Dependent on claim 32
39	Dependent on claim 54

41	Dependent on claim 31
43	Dependent on claim 54
44	Dependent on claim 43
45	Dependent on claim 44
46	Dependent on claim 44
47	Dependent on claim 43
48	Dependent on claim 47
49	Dependent on claim 47
54	Independent
55	Dependent on claim 20
56	Independent
57	Dependent on claim 56

IV. STATUS OF AMENDMENTS

No amendment to the claims was filed subsequent to the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A. Claim 54

The invention recited in claim 54 is a stent including a plurality of hoops aligned along a common axis. Each of the hoops is non-helical and oriented in a plane that is substantially perpendicular to the longitudinal axis of the stent. Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices that point in a direction along the longitudinal axis of the stent. The stent also includes means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

For example, and for purposes of illustration only, one exemplary embodiment of the invention is shown as stent 10 in Fig. 1A (page 19, lines 5-7; page 22, lines 17-18). Part of a stent such as stent 10 is also shown in Figs. 2A (page 19, lines 11-13; page 23, lines 11-12), 3 (page 19, lines 17-19; page 25, line 27-page 26, line 1), and 4A (page 19, lines 20-22; page 22, lines 17-18). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). Each hoop is non-helical and is oriented in a

plane that is substantially perpendicular to the longitudinal axis of the stent (page 9, lines 15-19, 13-19; page 10, lines 16-17).

Each of the hoops includes a plurality of elongate elements that are joined to one another and form apices such as apices 22 (Fig. 2A, page 23, lines 11-20) that point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

The stent also has means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop (page 10, lines 16-23 and Figs. 1A, 1B, 2A, 4A-4F). This feature is recited in terms of means plus function under 35 U.S.C. § 112, sixth paragraph. Pursuant to 37 C.F.R. § 41.37(c)(1)(v), the following paragraphs set forth exemplary structures described in the specification as corresponding to the claimed function.

The securing means may comprise a loop element of a suture material, for example, to tie the abutting juxtaposed apices together. The loop element may also comprise a loop formed of a thermoplastics material such, for example, as polypropylene. Alternatively, the securing means may be a bead formed of a thermoplastic material around juxtaposed apices. Also alternatively, the securing means may be a loop, ring, or staple formed of wire such as nitinol (page 10, lines 20-28). FIGS. 4B-4F are partial exploded views of embodiments of a stent illustrating exemplary means for securing juxtaposed apices of the stent (page 20, lines 1-4).

Referring to Fig. 4A, for example, abutting juxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 which may be, for example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has an abutting juxtaposed apex of a neighboring hoop 20 is tied to the abutting juxtaposed apex 22 in this embodiment. In other embodiments of the invention, only some of the juxtaposed apices 22 may be secured in this way (page 25, lines 4-11).

In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in FIG. 4B. The securing means may also comprise a bead 99b

formed of a thermoplastic material around juxtaposed apices, as shown in FIG. 4C. Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in FIGS. 4D, 4E, and 4F respectively (page 25, lines 12-21).

The foregoing, exemplary structures correspond to the function recited in claim 54 of securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop. Equivalent structures for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop are also within the literal scope of claim 54 under 35 U.S.C. § 112, sixth paragraph.

B. Claim 56

The invention recited in claim 56 is a stent including a tubular member that has a plurality of hoops aligned adjacent one another along the longitudinal axis of the tubular member. Each of the hoops has a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices that axially point in a direction along the longitudinal axis of the stent. At least some of the vertices axially abut and are individually connected to oppositely pointed veritices of elongate elements of an adjacent hoop. The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member.

For example, and for purposes of illustration only, and according to one exemplary embodiment of the invention, a stent such as stent 10 includes a tubular member (page 8, lines 8-10). The stent includes a plurality of hoops. For example, the exemplary proximal part 12 of stent 10 (Fig. 1A) is formed of a plurality of hoops such as hoops 20 (Figs. 1A, 2A; page 23, lines 11-15; page 24, lines 8-13). The exemplary hoops are aligned adjacent one another along the longitudinal axis of the tubular member (Fig. 1A; page 9, lines 19-27; page 23, lines 24-27).

Each of the hoops includes a plurality of elongate elements. Pairs of the elongate elements meet one another and form vertices such as vertices 22 (Fig. 2A, page 23, lines 11-20) that axially point in a direction along the longitudinal axis of the stent (page 9, lines 19-27; page 23, lines 24-27).

At least some of the vertices axially abut (Figs. 2A, 4A) and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop (Figs. 2A, 4A). For example, a loop element of a suture material connects oppositely pointed vertices of adjacent hoops (page 10, lines 18-23). Exemplary suture material is shown as element 99a in Fig. 4B (page 25, lines 13-15). Other materials for connecting oppositely pointed vertices of adjacent hoops are shown in Figs 4A and 4C to 4F (page 25, lines 4-21).

The vertices of each hoop that are pointed in the axial direction lie in a common plane that is perpendicular to the longitudinal axis of the tubular member (page 9, lines 15-19; page 10, lines 2-5).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The following provides a concise statement of each ground of rejection presented for review:

Whether claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 are unpatentable under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, as set forth in the Final Office Action.

VII. ARGUMENT

Paragraph 4 of the Final Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. It generally contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Paragraphs 5-7 of the Final Office Action provide more specific reasons for the rejections. Paragraph 2 of the Final Office Action explains why the Examiner disagreed with Applicants' arguments regarding claims 56 and 57 in their December 26, 2007 Request for Reconsideration.

EXAMINATION REQUIREMENTS TO SUPPORT A
REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

"An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP § 2163, Rev. 5, Aug. 2006, p. 2100-166. "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP §2163.02. In addition to not requiring *in haec verba* claims, the MPEP states that newly added claim limitations may be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163, p. 2100-168. "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163, p. 2100-169.

"The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." MPEP § 2163 II.A., p. 2100-169. *Accord*, MPEP § 2163 II.A.3(b), p. 2100-177. "Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention." MPEP 2163 II.A.2, p. 2100-171 (citation omitted) (emphasis added).

"In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

(A) Identify the claim limitation at issue; and

(B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention claimed in view of

the disclosure of the application as filed." MPEP §2163 III.A., p. 2100-178; § 2163.04 I.

THE REJECTION OF CLAIM 54 AND ITS DEPENDENT CLAIMS 20, 22-25, 27-33, 39, 41, 43-49, and 55

Contrary To The Final Office Action's Contention, The Disclosure Does Support "Means For Securing An Apex Of One Hoop To An Abutting Juxtaposed Apex Of A Neighboring Hoop"

Paragraph 5 of the Final Office Action has rejected these claims because independent claim 54 recites vertices that abut which, in the Examiner's view, is not disclosed in the specification. Instead, the Examiner contends that the specification only discloses juxtaposed vertices, which, he contends, may or may not imply contact.

Claim 54 recites, in part, "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) implicitly and inherently supports these claim limitations. The Examiner, on the other hand, has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

The specification states, in part

> Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together. . . . (page 10, lines 16-23)

This passage states that an apex of one hoop is secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently. The Examiner has not provided any evidence or reasons demonstrating that a person skilled in the art at the time the application was filed would not have recognized that the inventors were in possession of the claimed invention in view of the above passages in the disclosure.

One skilled in the art would also recognize that claim 54 finds clear support in stent embodiments such as those selected for illustration in Figs. 1A, 1B, 2A, 4A, and 4B-4F. (page 19, lines 11-12, 20-21). These figures clearly show embodiments having "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." The Examiner has not explained why a person skilled in the art would not recognize that the figures show this feature.

As stated above, the subject matter of a claim need not be described *in haec verba*. Consideration of the specification and the figures, undertaken from the standpoint of one of skill in the art, "conveys with reasonable clarity" that Applicants were in possession of the claimed invention. MPEP § 2163, p. 2100-169.

In contrast, the Examiner has not presented evidence or reasons why a person skilled in the art would not recognize that the written description of the invention, including the figures and passages specifically identified above, supports claim 54. Paragraph 5 of the Final Office Action states: "[t]he specification only discloses juxtaposed vertices." This statement fails to provide evidence that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention. It fails to recognize the embodiments described by the specification and the figures.

Paragraph 5 of the Final Office Action also contends that "the attachment mechanisms at page 10 lines 16-23 do not imply the apices must abut (as a weld or adhesive means would imply)." The Examiner's contentions disregard not only page 10, lines 16-23 but also other significant aspects of Applicants' disclosure and

fail to present required evidence demonstrating that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention.

Applicants' specification also states:

> [J]uxtaposed apices 22 of neighboring hoops 20 are secured together by securing means 99 (see Figure 4(a)), which are, in this example, 0.003" polypropylene filaments. Each apex 22 of each hoop 20 which has a juxtaposed apex of a neighboring hoop 20 is tied to the juxtaposed apex 22. (page 25, lines 4-9)
>
> In addition to polypropylene filaments, the securing means may comprise a loop element 99a of a suture material, for example, to tie the juxtaposed apices together, as shown in Fig. 4(b). The securing means may also comprise bead 99b formed of a thermoplastic material around juxtaposed apices, as shown in Fig. 4(c). Also alternatively, the securing means may be a loop 99c, ring 99d, or staple 99e formed of wire such as nitinol, as shown in Fig. 4(d), 4(e), and 4(f) respectively. (page 25, lines 12-21).

These passages explain the relationship of juxtaposed apices that can be tied together or secured together as shown in Figures 4A through 4F, each of which also shows an embodiment having abutting apices. Taken together, the disclosure's statement that juxtaposed apices can be tied together or secured together, along with Figures 4A through 4F, combined with the explanation that "each hoop is supported by its neighbors" would inexorably lead one skilled in the art to conclude that the juxtaposed apices of at least some disclosed embodiments are abutting. The Examiner has not presented any evidence to the contrary.

For all of the above reasons, Applicants' specification discloses "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop."

Addendum: With regard to the "verticies that abut" language of claim 54, the Examiner's Answer dated September 30, 2009 continues the argument

previously set forth in the Final Office Action. Applicant maintains that the specification clearly provides support for the language used in claim 54.

For example, as stated above, the disclosure provides that an apex of one hoop is secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently, particularly in view of Figures 4A through 4F, each of which shows an embodiment having abutting apices.

Claim 54 also recites, in part,

> a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

Paragraph 6 of the Final Office Action has rejected claim 54 and its dependent claims "because independent claim 54 recites 'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." In the Examiner's view, "[t]he specification only disclose [sic] embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical 'offset' feature."

Applicants' specification expressly describes two alternative categories of embodiments of hoops -- helical and substantially perpendicular. The specification states:

> In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent. (page 9, lines 13-19)

One of ordinary skill in the art would recognize that the specification conveys with reasonable clarity a plurality of embodiments and features. One described

embodiment is a helical configuration. One of ordinary skill in the art would recognize that the alternative to the helical embodiment described in the specification is not helical because the specification describes an alternative to a helical embodiment. That is, one of ordinary skill in the art would recognize that at least one alternatively described embodiment is non-helical.

This portion of the specification also makes clear that embodiments of Applicants' invention may be helical or perpendicular: "[t]ypically, the stents of this invention [are] of the helical or perpendicular variety." (page 10, lines 16-17). The phrase "helical or perpendicular variety" confirms that the "perpendicular variety" embodiment is an explicitly disclosed example of a non-helical alternative to the helical variety.

As indicated above, paragraph 6 of the Office Action contends that the application does not disclose "'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." To the contrary, the specification does disclose such an embodiment (although not *in haec verba*) by stating:

> Typically, the stents of this invention . . . of the . . . perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. (page 10, lines 16-20)

One of ordinary skill in the art would recognize that this paragraph also provides support for the claimed combination.

In paragraph 2, at the top of page 3[1], the Final Office Action indicates that it has interpreted "non-helical" to require that the claimed embodiment "lack[s] **any** helical features." Based upon this interpretation of "non-helical," the Examiner contends that Fig. 4A shows "a helical aspect (i.e. the longitudinal displacements described at page 23 lines 24-27)."

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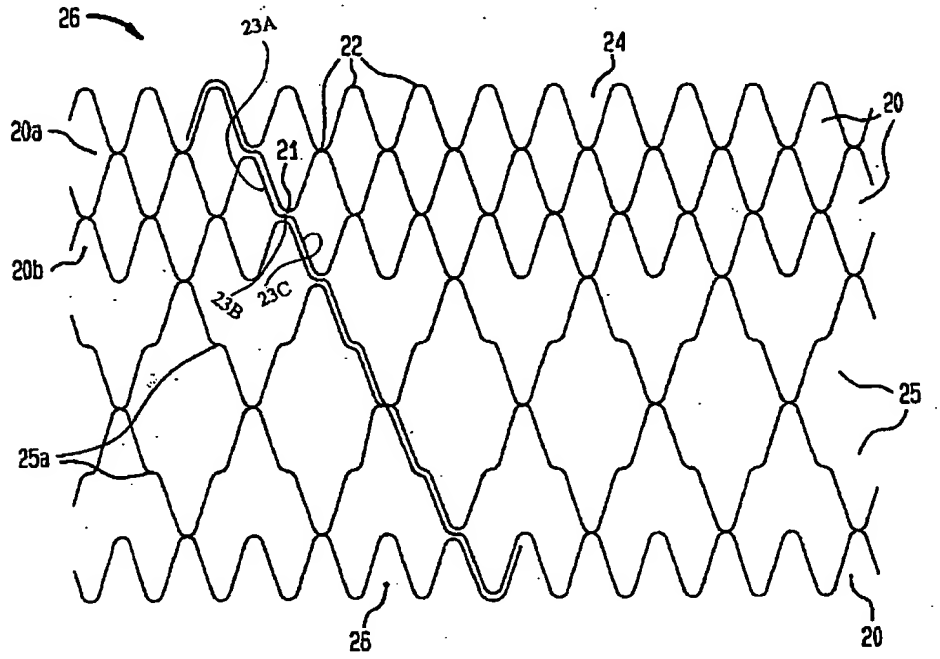
[1] The opening sentence of paragraph 2 of the Final Office Action states that it only pertains to claims 56 and 57. Since claims 56-57 do not contain a "non-helical" recitation, the Examiner's contentions regarding "non-helical" must pertain to claim 54.

But page 23, lines 24-27 describes Figs. 2A and 2B, not Fig. 4A, and describes how hoops 20a and 20b in those figures are formed. Figs. 2A and 2B are reproduced below, with reference numbers 23A, 23B and 23C added to Fig. 2A for the Board's ease of reference.

FIG. 2A



The referenced portion of the specification states:

> When one hoop 20 e.g. the hoop indicated at 20a has been formed, the point of winding of the nitinol wire is displaced longitudinally with respect to the axis of mandrel 46 to form the next successive hoop 20b.

Hoops 20a and 20b are shown in both figures.

Part of hoop 20a is formed by wire portion 23A. In order to form the adjoining hoop 20b, the point of winding of wire portion 23A is displaced longitudinally at wire portion 23B, and becomes wire portion 23C. Apparently, the Examiner contends that wire portion 23B precludes Applicants from reciting "hoops being non-helical." The Examiner is wrong.

The recitation at issue is: "**hoops** being non-helical." Figs. 1A, 1B, 2A, 3, 4A all show embodiments of non-helical **hoops**. Regardless of how the hoops are

formed, and regardless of how one hoop flows into another hoop, the **hoops themselves** are non-helical. The disclosure therefore supports "**hoops** being non-helical."

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

Addendum: With regard to the "non-helical" language of claim 54, the Examiner's Answer dated September 30, 2009 states that the disclosure on page 9 of the specification that is cited above does not indicate an embodiment having non-helical features. Applicant strongly rebuts this assertion. The specification states "Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms **a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent**. (page 9, lines 13-19) emphasis added. A helix is defined as "something spiral in form" (Merriam-Webster Online Dictionary. 2009). What is described above is clearly not spiral in form and therefore is clearly non-helical.

THE REJECTION OF CLAIM 56 AND ITS DEPENDENT CLAIM 57

Contrary To The Final Office Action's Contention, The Disclosure Does Support "At Least Some Of Said Vertices Axially Abut"

Claim 56 recites, in part,

> at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop.

In addition to the contentions stated in paragraph 4 of the Final Office Action, the Examiner's reasoning is further explained in paragraph 2 of the Final Office Action, which contends that

> the use of "a suture loop" to tie adjacent or juxtaposed apices does not expressly, implicitly, or inherently require contact between the apices. In fact, the teachings at page 10, lines 16-23 raise the

question of how tightly or loosely the suture is tied. These teachings are not equivalent to a connection created by adhesive or welding.

As was the case regarding claim 54, even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) expressly, implicitly, and inherently supports these claim limitations. In addition, the Examiner has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

As Applicants argued above regarding the rejection of claim 54, the specification describes, and the figures illustrate, embodiments in which "each hoop is supported by its neighbors" (page 10, line 20), "vertices . . . are individually connected to oppositely pointed vertices" using various connecting elements (page 10, lines 23-29; page 25, lines 4-9, 12-21), and apices are tied together. See also, Figs. 1A, 1B, 2A, and 4A-4F.

Taken together, the specification and the figures demonstrate that "at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop."

The Final Office Action has disregarded the above-described teachings in the specification because, in its view, the teachings "are not equivalent to a connection created by adhesive or welding." This statement makes the unsupported assumption that any two things (including juxtaposed apices) can abut only if they are connected by adhesive or welding or only if they are connected by something that is equivalent to adhesive or welding. The Board must reject these contentions because the Examiner has not supported them with any evidence and because they are clearly wrong. For example, a pencil resting on a desk top abuts the desk top even though the pencil is not connected to the desk top at all or by adhesive, welding, or anything equivalent to adhesive or welding. Applicants' disclosure demonstrates embodiments in which apices abut, even though the disclosure does not expressly refer to adhesive or welding.

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention.

Addendum: With regard to the "at least some of said vertices axially abut" language of claim 56, the Examiner's Answer dated September 30, 2009 continues the argument previously set forth in the Final Office Action. Applicant maintains that the specification clearly provides support for the language used in claim 54.

For example, as stated above with respect to the addendum added to the discussion of claim 54 regarding the abutting language used therein, the disclosure provides that an apex of one hoop can be secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently, particularly in view of Figures 4A through 4F, each of which shows an embodiment having abutting apices.

Claim 56 also recites, in part:

> vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Paragraph 7 of the Final Office Action has rejected claims 56 and 57 because, in the view of the Examiner, the specification does not provide support for the recitation that vertices of "each hoop" lie in a common plane perpendicular to the longitudinal axis of the tubular member. In the view of the Examiner, the specification only supports a recitation that for the perpendicular embodiment apices of "one or more" hoops lie in such a plane. The Final Office Action also contends that only a recitation of "substantially perpendicular" is supported by the description of Figs. 1-4. Applicants disagree.

The specification contains broad language generally describing selected embodiments of its disclosed stents as being of a "perpendicular variety." (page 10, line 17) One exemplary embodiment may have hoops that are "substantially perpendicular to the longitudinal axis" (page 23, lines 21-22, discussing Fig. 2A).

Other exemplary embodiments of the perpendicular variety are straight stents (page 44, lines 19-20) having hoops that are "perpendicular to a common axis." (page 44, lines 22-23, discussing Figs. 22 and 23).

Figs. 1A and 2A, among other figures, illustrate an embodiment of a stent 10 (page 22, lines 17-18) having hoops 20. (page 23, line 11-page 24, line 13). "Each hoop 20 is wound onto mandrel 46 such that the plane of the circumference of each hoop 20 is substantially perpendicular to the longitudinal axis of the mandrel." (page 23, lines 20-23)

Fig. 22 illustrates another embodiment of a stent using configurations such as the stent configurations described in Figs. 1A and 2A. Fig. 22 illustrates, for example, a stent embodiment having a proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). The stent embodiment illustrated in Fig. 22 also has a distal portion 402 having additional similar hoops 20. (page 45, lines 10-12). This embodiment is also a stent of the "perpendicular variety." (page 44, lines 21-23) ("each of the requests comprising one or more adjacent hoops, perpendicular to a common axis").

Since the stent embodiment shown in Figs. 1A, 2A and stent embodiments shown in Figs. 22, 23 are both of the "perpendicular variety," and since both stents may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops.

In addition, Fig. 1A, illustrating stent embodiment 10, clearly shows "vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." As indicated by the MPEP, the PTO must consider Applicants' figures when construing their full disclosure. The specification cannot be considered in a vacuum, without giving full weight to the clear teachings of the figures.

Page 3 of the Final Office Action has mischaracterized Applicants' arguments. Applicants have not suggested that "it would be obvious to interchange features of the Figure 1a/2a embodiment and Figure 22/23 embodiments." As explained above, Fig. 22 illustrates, for example, a stent embodiment having a

proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). As stated above, therefore, since both stent embodiments may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of perpendicular hoops. Contrary to the belief of the Examiner, therefore, one skilled in the art would understand that the specification does interrelate at least Figs. 1-4 with at least Figs. 22 and 23. The Final Office Action fails to demonstrate that one skilled in the art would not have such an understanding.

For the above reasons, Applicants' disclosure fully supports the phrase "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member."

Addendum: With regard to the language "vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member" of claim 56, the Examiner's Answer dated September 30, 2009 states that the two embodiments illustrated in Figures 1A/2A and 22/23 do not support such language. Applicant strongly rebuts this assertion.

First, the Examiner admits at page 7 of the Examiner's Answer that the specification describes the relevant elements in Figures 1A/2A as "substantially perpendicular". Applicant asserts that one of ordinary skill in the art would understand what the claim language of claim 56 means even if it was only based upon this disclosure regarding Figures 1A/2A, however, the specification also provides other disclosures regarding perpendicular and perpendicular variety as discussed herein.

Further, the Examiner argues that the specification only discusses "'perpendicular hoops' in the context of 'one or more hoops' rather than 'each or all hoops'". Applicant asserts that the meaning of "one or more hoops" includes "each hoop" and "all hoop" type configurations contrary to Examiner's argument.

For example, as discussed previously above, the specification states "Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of **each hoop is substantially perpendicular** to the longitudinal axis of the stent."

(page 9, lines 13-19) emphasis added. As applied to the "one or more hoops" language, this clearly supports the language of claim 56 as it would be viewed by one of ordinary skill in the art. Further, as stated above, the terms "perpendicular" and of a "perpendicular variety" have been used elsewhere in the specification which clearly indicate to the reader that "perpendicular" is within the scope of potential claim language.

The Examiner also argues that Figures 2A, 3, and 4A prevent a truly perpendicular hoop of vertices, however, as stated above, the disclosure on Applicant's page 9 provides that the hoops are substantially perpendicular and that the language of the specification would indicate to the reader that "perpendicular" is within the scope of potential claim language.

Lastly, the Examiner argues that the disclosure describing Figures 22-23 as having one or more perpendicular hoops only describes the vertices on the ends of the stent. Such a discussion is irrelevant as the arguments provided above fully support use of the term "perpendicular".

CONCLUSION

In view of the foregoing remarks, Applicants submit that the grounds for rejection of claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 are improper. Applicants respectfully request that the Board reverse the Examiner's rejection of all pending rejected claims.

CONCLUSION

Appellants respectfully submit that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner and/or members of the Board are invited to telephone Appellants' attorney Jeffery L. Cameron at (612) 236-0121 to facilitate this appeal.

CERTIFICATE UNDER 37 C.F.R. §1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: **MS Appeal Brief-Patents** Commissioner for Patents, P.O. BOX 1450, Alexandria, VA 22313-1450, on this 30th day of November, 2009.

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VIII. CLAIMS APPENDIX

1-19 (Canceled)

20. (Previously Presented) A stent as recited in claim 54 comprising at least one stent segment in combination with one or more additional stent segments.

21. (Canceled)

22. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are axially aligned with one another.

23. (Previously Presented) A stent as recited in claim 20 wherein said one or more additional segments are secured to one another by connecting means connecting at least some of the apices of hoops at mating ends of said stent and said additional segments.

24. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of the same diameter.

25. (Previously Presented) A stent as recited in claim 20 wherein adjacent hoops are of a different diameter.

26. (Withdrawn) A stent as recited in claim 22 wherein said axially aligned segments are connected to one another by a tubular fabric element.

27. (Previously Presented) A stent as recited in claim 20 wherein a first additional segment is axially parallel to, but non-common co-axial with, said stent segment.

28. (Previously Presented) A stent as recited in claim 27 further comprising a second additional segment axially parallel to said stent segment, but non-co-axial with either said stent segment or said first additional stent segment.

29. (Previously Presented) A stent as recited in claim 28 wherein at least one of said first and second additional stent segments is of frustoconical shape and is further combined with a third an additional stent segment, one end of which includes a mating frustoconical shape.

30. (Previously Presented) A stent as recited in claim 29, wherein said mating frustoconical stent segments are adapted to be separately placed in a bifurcated artery and then, by expansion of one of said frustoconical stent segments, secured to one another.

31. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said hoops are formed of a single continuous wire.

32. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

33. (Previously Presented) An endoluminal stent as claimed in claim 32 wherein said suture is a tied loop of thermoplastic material.

34. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a suture.

35. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is a staple.

36. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is wire twisted into loop.

37. (Withdrawn) An endoluminal stent as claimed in claim 36 wherein said wire is nitinol.

38. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said securing means is bead of thermoplastic material.

39. (Previously Presented) An endoluminal stent as claimed in claim 54 wherein each longitudinal end of the stent is substantially perpendicular square to the longitudinal axis of the stent.

40. (Withdrawn) An endoluminal stent as claimed in claim 54 wherein said stent is at least partially covered in fabric.

41. (Previously Presented) An endoluminal stent as claimed in claim 31 wherein said wire is nitinol.

42. (Canceled)

43. (Previously Presented) An endoluminal stent as claimed in claim 54 further comprising a radiopaque marker disposed on at least one end of the stent.

44. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque element attached to one end of said stent.

45. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a platinum wire.

46. (Previously Presented) An endoluminal stent as claimed in claim 44 wherein said element is a gold wire.

47. (Previously Presented) An endoluminal stent as claimed in claim 43 wherein said radiopaque marker comprises a radiopaque tube disposed around a part of said stent.

48. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is platinum.

49. (Previously Presented) An endoluminal stent as claimed in claim 47 wherein said tube is gold.

50-53. (Cancelled)

54. (Previously Presented) A stent comprising:

a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the stent; and

means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop.

55. (Previously Presented) A stent as recited in claim 20 wherein at least one of said additional stent segments comprises:

a plurality of hoops aligned along a common axis, each of said hoops oriented in a plane substantially perpendicular to the longitudinal axis of the additional stent segment, and each of said hoops including a plurality of elongate elements joined to one another and forming apices that point in a direction along the longitudinal axis of the additional stent segment; and

means for securing an apex of one hoop to a juxtaposed apex of a neighboring hoop.

56. (Previously Presented) A stent comprising a tubular member having a plurality of hoops aligned adjacent one another along the longitudinal axis of said tubular member, each of said hoops comprising a plurality of elongate elements, with pairs of said elongate elements meeting one another and forming vertices axially pointing in a direction along the longitudinal axis of the stent, wherein at least some of said vertices axially abut and are individually connected to oppositely pointed vertices of elongate elements of an adjacent hoop, wherein the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

57. (Previously Presented) A stent according to claim 56, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

58. (Withdrawn) A method of reinforcing a body vessel using a tubular sheath disposed between an entry location in a body and an implantation location, said method comprising the steps of:

a. providing a stent as recited in claim 56;

b. compressing the stent into its compressed configuration;

c. inserting the compressed stent into the tubular sheath;

d. delivering the compressed stent through the tubular sheath to the implantation location; and

e. withdrawing the sheath while holding the stent at the implantation location within the vessel and expanding the stent within the implantation location as the sheath is withdrawn by permitting the self-expandable stent, as the constraint of the sheath is removed to return to said expanded configuration;

whereby the stent is securely disposed in the implanted state against said body vessel.

59. (Withdrawn) A method according to claim 58, wherein said stent is comprised of a shape memory material.

60. (Withdrawn) A method according to claim 59, wherein said shape memory material is nitinol and step (b) is performed at low temperature.

61. (Withdrawn) A method according to claim 58, wherein at least one elongate element in each hoop is a continuation of an elongate element of an adjacent hoop.

62. (Withdrawn) A prosthesis for placement in a body lumen comprising a tubular graft supported and adapted to be retained in said lumen by a stent as recited in claim 56.

IX. EVIDENCE APPENDIX

None.

X. RELATED PROCEEDINGS APPENDIX

Tab 1 Judgment of the Board of Patent Appeals and Interferences in Interference No. 104,083.

Tab 2 Final Decision and Judgment of the Board of Patent Appeals and Interferences in Interference No. 104,192.

Tab 3 11/15/01 Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 4 12/21/01 Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 5 5/2/02 Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 6 8/30/03 Memorandum Opinion and Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 7 3/25/04 Stipulation and Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 8 9/12/04 Protective Order, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 9 12/14/04 Joint Stipulated Request To Extend Discovery, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 10 3/31/06 Memorandum Opinion, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 11 3/31/06 Final Judgment, Scimed Life Systems, Inc. v. Medtronic Vascular, Inc., et al., U.S. District Court for the District of Columbia, Civil Case No. 01-2015 (RJL).

Tab 12 8/8/07 Decision, Boston Scientific Scimed, Inc. (formerly known as Scimed Life Systems, Inc.) v. Medtronic Vascular, Inc. (also known as Medtronic AVE, Inc.), U.S. Court of Appeals for the Federal Circuit, No. 2006-1434.